



**UNITED STATES DEPARTMENT OF COMMERCE**  
**Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

09/116,676 07/16/98 ADHAM

N 53801/JPW/KD

EXAMINER

HM12/1106

JOHN P WHITE  
COOPER & DUNHAM  
1185 AVENUE OF THE AMERICAS  
NEW YORK NY 10036

D HARA, E

ART UNIT

PAPER NUMBER

1646

DATE MAILED:

11/06/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

## Office Action Summary

Application No.

09/116,676

Applicant(s)

Adham

Examiner

Eileen B. O'Hara

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 02 July 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-9, 14-48, 150, 208, 209, 213, 214, 218-220 and 222-228 is/are pending in the application.
- 4a) Of the above claim(s) 1-9, 14-48 and 150 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 208, 209, 213, 214, 218-220 and 222-228 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-9, 14-48, 150, 208, 209, 213, 214, 218-220 and 222-228 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## **DETAILED ACTION**

### ***Continued Prosecution Application***

1. The request filed on August 13, 2001 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/116, 676 is acceptable and a CPA has been established. An action on the CPA follows.

### ***Status of Claims***

2. Claims 1-9, 14-48, 150, 208, 209, 213, 214, 218-220 and 222-228 are pending in the instant application. Claim 222 has been amended and claim 221 has been canceled as requested by Applicant in Paper Number 13, filed July 2, 2001.

Claims 1-9, 14-48 and 150 are withdrawn as being drawn to a non-elected invention.

Claims 208, 209, 213, 214, 218-220 and 222-228 are currently under examination.

### ***Withdrawn Rejections***

3.1 The declaration filed on July 2, 2001 under 37 CFR 1.131 is sufficient to overcome the Chang et al. reference.

3.2 Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

Art Unit: 1646

***Claim Objections***

4. Claims 226 and 228 are objected to because of the following informalities: in section (b) of both claims, the first and second sub-sections are labeled (iii) and (iv) or (v) and (vi), and there are no sub-sections (i) and (ii) and/or (iii) and (iv) before them.

Claim 228 is also objected to because the word “contracting” on the first line of section (2) should be spelled “contacting”.

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5.1 Claims 222 and 223 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 222 and 223 encompass a method of obtaining a composition which comprises admixing a carrier and a chemical compound identified by the process of any of claims 224, 208, 209, 225, 226, 213, 214 or 227, **or a novel structural and functional analog or homolog** thereof. There is no disclosure in the specification of what a structural and functional analog or homolog of such a compound would be, and is therefore new matter.

Art Unit: 1646

5.2 Claims 222 and 223 are also rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are rejected for reciting the step “wherein said chemical compound has been recovered free of any soluble polypeptide”. There is no disclosure in the specification of this step, and is therefore new matter.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 208, 213, 214, 226 and 227 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6.1 Claim 208 is vague and indefinite because it is dependent upon claim 224, which is a method for determining whether a chemical compound specifically binds to a soluble polypeptide, and the detection method in claim 208 comprises detecting binding of an antibody to the soluble polypeptide, and it is not clear how detecting binding of an antibody to the soluble polypeptide will detect binding of a chemical compound to the soluble polypeptide.

6.2 Claim 213 is similarly vague and indefinite because it is dependent upon claim 226, which is a competitive binding assay for determining whether a chemical compound specifically binds to a soluble polypeptide, and the detection method in claim 213 comprises detecting binding of an antibody to the soluble polypeptide, and it is not clear how detecting binding of an antibody to the soluble polypeptide will detect binding of a chemical compound to the soluble

Art Unit: 1646

polypeptide, unless the antibody is the second chemical compound, which should be stated in the claim.

6.3 Claims 213, 214, 226 and 227 are indefinite because claim 226 encompasses a competitive binding assay, but as written, the first step of the assay could be interpreted as separately contacting the soluble polypeptide with the first and the second chemical compound. It is suggested that the word “separately” on the 21<sup>st</sup> line be replaced by the word “first”, and inserting the word “separately” in between “and” and “with only” on the 24<sup>th</sup> line of the claim.

6.4 Claims 222 and 223 are indefinite because of the word “novel” in claim 222. It is not clear from the claims what chemical compound would be novel and what wouldn’t be, making the claims vague and indefinite.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 222 and 223 remain rejected under 35 U.S.C. 102(b) as being clearly anticipated by any one of the Jackson et al, Verploegen et al. and Grasso et al. publications cited in the previous Office Action, Paper No. 11.

The reasons for the rejection were stated in the previous Office Action. Applicants traverse the rejection, and assert that the amendments to claim 222, which includes a separation step, eliminate the product-by-process limitation, and that the claimed process does distinguish

Art Unit: 1646

the identified compound from an identical compound which was not identified by the analytical method recited in these claims.

Applicants' arguments have been considered but are not persuasive. The claims are drawn to a method of obtaining a composition by admixing a compound identified by any of the processes of the recited claims with a (pharmaceutical) carrier, wherein the compound has been recovered free of any soluble polypeptide. The compositions of the prior art meet these limitations. For example, though Verploegen et al. is silent with respect to the leptin compounds being recovered free of any soluble polypeptide, the R128Q leptin compound was expressed in Sf9 insect cells, then purified by immunoaffinity chromatography using a mAB (2A5) directed against human leptin. Immunoaffinity chromatography is a method that produces extremely pure proteins, and the skilled artisan would appreciate that a protein purified from such a process would be free of soluble polypeptides. Therefore, the rejection under 35 USC § 102 is maintained.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 208, 209, 213, 214, 218-220 and 224-228 remain rejected under 35 U.S.C. 103(a) as being unpatentable over any one of the Jackson et al, Verploegen et al. and Grasso et al.

Art Unit: 1646

publications cited in the previous Office Action, Paper No. 11 and above, in view of Applicant's assertion on the record that the subject matter of these claims are obvious over the subject matter of claims 222 and 223.

Applicants traverse the rejection and assert that since claim 221 has been canceled and claim 222 has been amended, amended claim 222 contains patentable subject matter for the reasons stated in response to the rejection under 35 USC § 102 above, and that if claims 222 and 223 are patentable, then claims 208, 209, 213, 214, 218-220 and 224-228 are also patentable.

Applicants' arguments have been considered but are not persuasive. For the reasons discussed above under 35 U.S.C. 102(b), claims 222 and 223 are not patentable, and therefore the rejection of claims 208, 209, 213, 214, 218-220 and 224-228 are maintained.

It is believed that all pertinent arguments have been answered.

#### ***Advisory Information***

9. The use of the trademark "FLAG" has been noted in this application. It should be capitalized wherever it appears (for example, claim 226) and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

#### ***Conclusion***

10. No claims are allowed.



Art Unit: 1646

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (703) 308-3312.

The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

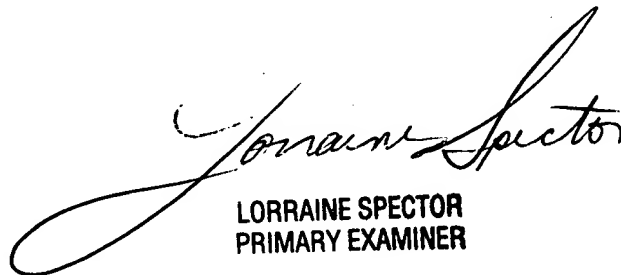
Official papers filed by fax should be directed to (703) 308-4242.

Informal papers filed by fax should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Eileen B. O'Hara, Ph.D.

Patent Examiner



LORRAINE SPECTOR  
PRIMARY EXAMINER